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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,442	02/18/2004	Chengde Wu	TEX4542P0491US	3434
32116	7590	01/25/2006	EXAMINER	
WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661			GRAZIER, NYEEMAH	
		ART UNIT	PAPER NUMBER	
		1626		

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,442	WU ET AL.	
	Examiner	Art Unit	
	Nyeemah Grazier	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 November 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8 is/are pending in the application.
 - 4a) Of the above claim(s) 4,5 and 7 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,6 and 8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/24/04.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION
FIRST ACTION ON THE MERITS

I. ACTION SUMMARY

5 Claims 1-8 are currently pending in the instant application and are subject to the required restrictions and elections as described below. Claims 1-3 and 6 and 8 in part and the whole of claims 4, 5, and 7 are withdrawn under 37 CFR 1.142(b) as non-elected subject matter.

II. PRIORITY

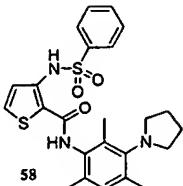
10 This application claims the benefit of U.S. Provisional Application Serial No. 60/448,791 filed on February 20, 2003 under 35 U.S.C. 119(e).

III. ELECTION

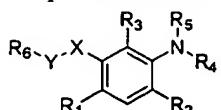
15 Applicant's election with traverse of Group III, claims 6 and 8; and provisional specie election of Compound 58 in the reply filed on November 14, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

20 Applicant has requested the examination of Compound 53, which is an isomer of compound 58. The Examiner will examine the compound 53 along with 58. The method claims, commensurate in scope with the elected subject matter, will, however, be rejoined when the compound and composition are in condition for allowance. M.P.E.P. § 804.01.

SCOPE OF THE ELECTED SUBJECT MATTER BASED ON SPECIE ELECTION



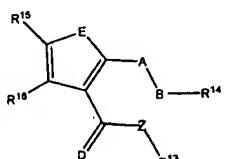
5 Applicants have elected the above compound as a provisional specie election for search purposes. (See Response to Restriction, p. 1). Thus, the elected invention for search and examination purposes is the products of Formula (I) wherein:



10 R₁, R₂, R₃, R₇, R₈, and R₉ are defined in claim 1;
X is nitrogen;
Y is CO;
R₄ and R₅ taken with N can form an unsubstituted saturated 5 membered ring;
R₆ is thiophene ring substituted at the 2 position with -NH-arylsulfonyl and wherein aryl
15 is a carbocyclic ring;

The elected invention for search and examination purposes is the products of Formula (II)

wherein:



E is sulfur;
20 D is oxygen or sulfur;
Z is NR₁₃ and R₁₃ is phenyl substituted with N-linked pyrrolidinyl;
A is selected from the group NR₁₇ or SO₂;

B is selected from the group NR₁₇ or SO₂;

When A is NR₁₇, B is SO₂ and when A is SO₂, B is NR₁₇;

R₁₄ is phenyl.

5 SCOPE OF WITHDRAWN SUBJECT MATTER NOT DRAWN TO THE ELECTED INVENTION

The remaining subject matter of claims 1-3, 6 and 8 in part stands withdrawn under 37 CFR § 1.142(b) as being for non-elected subject matter. The compounds are not within the elected invention, which are independent and distinct from the elected invention and do not have utility with the elected compound and are therefore withdrawn by way of restriction.

10 The compounds withdrawn by way of restriction are the compounds of Formula (I) wherein: X is CH₂ or O; Y is selected from the group consisting of SO₂, CH₂SO₂, CH₂CO, NHCO, OCO and NHSO₂; R₄ is selected from the group C₁₋₆alkyl, aryl, aralkyl and heteroaryl; R₅ is the same as R₁ or Z-NR₇R₈ or R₄ and R₅ taken with N can form a 6-membered ring; Z is (CH₂)_n; R₆ is aryl, heteroaryl (EXCEPT thiophene) and ZNR₇R₈; and R₁, R₂, R₃, R₇, R₈, and R₉ 15 are defined in claim 1; and Formula (II) wherein: E is NR₁₁, O, CR₁₁=CR₁₂, CR₁₁=N, where R₁₁ and R₁₂ are recited in claim 6; D is NR₁₀; Z is CR₁₃ and R₁₃ is as recited in claim 6; A is selected from the group C=O or wherein A is NR₁₇ and B is CO₂ or CR₁₈ or when A is C=O and B is NR₁₉; R₁₃ and R₁₄ are independently H, alkyl, heteroaryl.

20 The abovementioned compounds are withdrawn from consideration as being non-elected subject matter. The withdrawn compounds contain distinct substitutions such as wherein R₅ and R₄ together with nitrogen form a 6 membered ring (piperidine), which differ significantly in structure and function. This structural and elemental variety of substitutions is exemplified by

their classifications in the U.S. classification system. For example: piperidines are classified in 546 while pyrrolidines are classified in 548, etc. Therefore the compounds are withdrawn as being non-elected subject matter that differs materially in structure and composition.

5

EXTENDED PRIOR ART SEARCH PURSUANT TO MPEP 803.02

If upon examination of the elected species, no prior art is found that would anticipate or render obvious the instant invention based on the elected species, the search of the Markush-type claim will be extended. See M.P.E.P. § 803.02 (2001). If prior art is then found that anticipates or renders obvious the non-elected species, the Markush-type claim will be rejected. It should be 10 noted that the prior art search will not be extended unnecessarily to cover all non-elected species. Should Applicant overcome the rejection by amending the claim, the amended claim will be reexamined. Id. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. Id. In the event prior art is found during reexamination that renders obvious or anticipates the amended Markush-type claim, the claim will be rejected 15 and the action made final. Id.

As indicated above, Examiner searched the compound based on the elected species, Compound 58 in response to the requirement to restrict the products of Formula (II), wherein: “E” is sulfur; A is NH and B is SO₂ or A is SO₂ and B is NH; D is oxygen; Z is NH; R13 is 1, 3, 5 methyl, 2-pyrrolidine; R15 and R16 are hydrogen; and R14 is phenyl. However, there was no 20 prior art of record that anticipated or rendered obvious the elected species and therefore the scope of the subject matter was **extended or broaden** in pursuant to M.P.E.P. § 803.02. *supra*.

The prior art search was extended to include some of the non-elected species wherein the variable are defined as follows: Formula I wherein R4 and R5 are alkyl; R₁, R₂, R₃, R₇, R₈, and R₉ are defined in claim 1; X is nitrogen; Y is CO; R₆ is thiophene substituted NH-SO₂-phenyl or SO₂-NH-phenyl. Formula II wherein **R₁₄** selected from aryl or heteroaryl ring; E is sulfur; D is oxygen or sulfur; Z is NR₁₃ and R₁₃ is phenyl; A is selected from the group NR₁₇ or SO₂; B is selected from the group NR₁₇ or SO₂; When A is NR₁₇, B is SO₂ and when A is SO₂, B is NR₁₇.

5
V. **REJECTIONS**

Claim Rejections - 35 USC § 112

10 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 (1) Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. The second paragraph of 35 USC 112 requires that the claims particularly point out the subject matter that applicant regards as the invention. A claim referring to the specification is improper except in rare instances. *See Ex parte Fressola*, 27 USPQ.2d 1608 (BPAI 1993).

20 Claim 1 recites R6 as inter alia, heteroaryl without specifying whether the heteroaryl is substituted or unsubstituted. In the specification, “heteroaryl” is defined as thienyl, for example, and that the heteroaryl is optionally substituted with “arylsulfonyl” and wherein said substituent is “attached directly by linkers.” (See Spec., p. 13, ll. 6-15). The “linkers are typically short chains of 1-3 atoms containing any combination of . . . -NH-.” (*Id.*). Applicant elected

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compound 58 as a specie. Thus, for examining purposes, R6 is interpreted to mean thiophene substituted at the 2 position by NH-SO₂-phenyl or SO₂-NH-phenyl.

Claim 6 recites R13 as "aryl." Again there is no mention of whether the group is substituted and no mention of the substitution on the aryl group. In the specification, "aryl" is 5 defined as carbocyclic group or a heterocyclic aromatic group which can be further substituted with heterocycle group which is defined on p. 12 of the specification (mind the objection to the typographical error on p. 12, line 18 where "heteroaryl" should be heterocycle). (See Spec, p.11, ll. 23-25; 13, ll. 6-15).

The abovementioned rejections under 35 U.S.C. § 112, 2nd paragraph will be obviated by 10 the following suggestions:

Applicant should amend the claim to read, for example: The compound of formula (I) wherein . . . R6 is a thiophene substituted at the 3 position with -C=O-NH-aryl wherein aryl is a carbocyclic ring and wherein the thiophene can be further substituted by one or more groups selected from the group consisting of alcohols, ethers, esters, amides, sulfones; 15 sulfides, hydroxyl, nitro, cyano, carboxy, amines, heteroatoms, lower alkyl, lower alkoxy, lower alkoxy carbonyl, alkoxy alkoxy, acyloxy, halogens, trifluoromethoxy, trifluoromethyl, alkyl, aralkyl, alkenyl, alkynyl, aryl, cyano, carboxy, carboalkoxy, carboxyalkyl, cycloalkyl, cycloalkylalkyl, heterocyclyl, alkylbeterocyclyl, heterocyclalkyl, oxo, arylsulfonyl and aralkylaminocarbonyl or any of the substituents of the preceding paragraphs or any of those 20 substituents either attached directly or by suitable linkers. The linkers are typically short chains of 1-3 atoms containing any combination of -C-, -C(O)-, -N-H-, -S-, -S(O)-, -O-, -C(O)O- or -S(O)O-. Rings may be substituted multiple times.

(2) Claims 1 and 2 recite "X" as "N" however it unclear because N must substituted with hydrogen or an R group.

5

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by *Schindler et al.* (U.S. 6,335,334 B1). The reference discloses sulfur substituted sulfonyl aminocarboxylic acid N-arylamides such as 4-[[3-[[4-chlorophenyl)sulfonyl]amino]-2-thienyl]carbonyl]amino]-15 benzesulfonyl fluoride. (See HCAPLUS hit 8 of 11, CAR Registry No. 254878-40-5) (attached).

Claims 1-3 and 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by *Wu et al*, *J. Med. Chem.* 1999, 42, 4485-99. The prior art discloses the instant invention of Formula II wherein R15 and R16 are hydrogen; E is sulfur, D is oxygen; Z is NH; R14 is substituted heteroaryl (1,2-oxazole ring); R13 is aryl (phenyl) and wherein the phenyl group is substituted: 20 (See compounds 7a-7aa, p. 4490; especially 7j disclosing pyrrolidinyl); and Formula I wherein R1, R2 and R3 are methyl; R5 and R4 together with N form a 5 membered ring; R4 and R5 are alkyl; X is NH and Y is SO₂; and R6 (noting definition for heteroaryl in Specification) is a heteroaryl substituted with phenyl and separated by the linker NH-SO₂.

Claims 1-3, 6 and 7 are rejected 35 U.S.C. 102(b) as being anticipated by Wu et al, WO 98/13366 A1 (April 2, 1998). *See e.g., Wu et al., WO 98/13366A1 at p. 55, ll. 14-16 which discloses N-(4-chloro-3-methyl-5-isoxazolyl)-2-(3-hydroxy-2,4,6-trimethylphenylaminocarbonyl) thuophene-3-sulfonamide; and p. 56, ll. 1-2 which discloses N-(4-chloro-3-methyl-5-isoxazolyl)-2-(3-pyrrolidinyl-2,4,6-trimethylphenylaminocarbonyl) thuophene-3-sulfonamide. See also, p. 103, ll. 25-26.*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

10 (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15 Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by *Weinstock et al.* (WO 02/28353 A2). The reference discloses a voluminous amount of 2-thiophenecarboxamide phenyl sulfonyl amino compounds and compositions thereof represented by the formulae I-III. (See HCAPLUS Hit 7 of 11, attached). See also, pp. 6-24 which teaches species of formulae I-III.

Provisional Obviousness-Type Double Patenting

20 Claims 1-3 and 6 and 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 8-10 and 12 of copending Application No. 10/924,180 (US 2005/049286A1). The rejection of claim 1-3 and 6

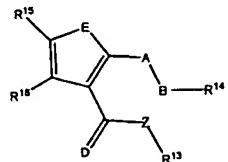
ad 8 over co-pending application 10/924,180 is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise 5 extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). See also M.P.E.P. § 804 (2001).

10 Obvious-type nonstatutory double patenting rejection is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. §103" with the distinction that the double patent rejection is not considered prior art. Id. See also *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Thus, the analysis employed in an obviousness-type double patent rejection is consistent with a §103(a) analysis set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 15 459 (1966).

Although the conflicting claims are not identical, they are not patentably distinct from each other because: Claims 1-3 recite the compounds and compositions of formula (I) wherein: R₁, R₂, R₃, R₇, R₈, and R₉ are defined in claim 1; X is nitrogen; Y is CO; R₄ and R₅ taken with N can form a 5 membered ring; R₆ is thiophene substituted with arylsulfonyl with -NH-linker. 20 Claim 2 depends from claim 1 and sets forth the additional limitations, namely that R1 and R2 are methyl and R3 is hydrogen; X is nitrogen; Y is SO₂ and R1 is 3,5-dichloro-2-hydroxybenzene.

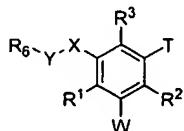
Claims 6 and 8 recite the compounds and compositions of formula (II) wherein:



E is sulfur; D is oxygen or sulfur; Z is NR₁₃ and R₁₃ is phenyl substituted with pyrrolidinyl; A is selected from the group NR₁₇ or SO₂; B is selected from the group NR₁₇ or SO₂; When A is NR₁₇, B is SO₂ and when A is SO₂, B is NR₁₇; R₁₄ is phenyl.

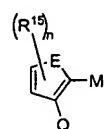
Determining the Scope and Contents of the Co-pending Application

Conflicting claims 1-3 recite the compounds and compositions of formula (I)

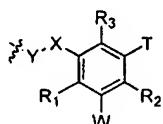


which include where X is NR19, Y is CO, T is NR4R5, R4 and R5 together with the nitrogen to which they are attached form a 5 membered ring, R6 is aryl and R19 is selected the group consisting of H, C1-C6 alkyl, aryl and aralkyl. (See pp. 93-94 of application 10/924,180).

Conflicting claims 8 and 9 recites the compounds of formula (III)



wherein E is sulfur, M or Q is A-B-G-R14 and the other has the structure :



R15 is alkyl, halogen, etc.; n is 0-4; A is NR17 where n is zero; G is NR17 where n is zero; B is SO2; and R14 is aryl.

Ascertaining the Differences Between the Copending Application and the Instant Claims

The difference between the instant claims and the copending application is that the claims in the copending application (10/924,180) is a genus of the compound of the invention in the instant application, which is a subgenus.

5

Resolving Level of Ordinary Skill in the Pertinent Art

The pertinent art is cardiovascular drug discovery and generally medicinal chemistry. One of ordinary skill in the pertinent art of medicinal chemistry, specifically, cardiovascular drug discovery would have the motivation to make and use to instant invention because there is motivation to make in the instant compounds in the abovementioned references which teach compounds useful for treatment of conditions associated with Urotensin-II imbalance. The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

The prima facie case for obviousness is derived from the structural similarities, specie claims and preferred embodiments Thus, there is motivation to one skilled in the art to make and use in the instant compounds and compositions with the expectation that they would both have the same pharmacokinetic effect.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

VI. ALLOWABLE SUBJECT MATTER

10 The allowable subject matter are the compounds and compositions of formula (I) wherein: R4 and R5 together with N form a 5 member ring, R1, R2 and R3 are as recited in claim 1; X is nitrogen; Y is CO and R6 is phenyl; and the compounds of formula (II) wherein: E is sulfur; D is oxygen, Z is NR₁₃; A is selected from the group NR₁₇ or SO₂; B is selected from the group NR₁₇ or SO₂; when A is NR₁₇, B is SO₂ and when A is SO₂, B is NR₁₇; R14 is phenyl
15 and R13 is Phenyl substituted by N-linked pyrrolidine.

VI. OBJECTIONS

Specification

The specification is objected to for the following informalities: Page 12 states the term
20 “heteroaryl.” It is believed that applicant meant to state “heterocycle.” Correction is required.

Claim Objections

Claim 6 is objected to because of the following informalities: Please insert a semicolon at the end of line 5 on page 82.

Claim Objection-Non Elected Subject Matter

Claims 1-3 and 6 and 8 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should rewrite the claims in independent form including all 5 of the limitations of the base claim and any intervening claims and if rewritten directed solely to the subject matter indicated as being examinable.

Dependent Claim Objections

Dependent Claims 2, 3 and 8 are also objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent 10 form and include the limitations of the base claim and any intervening claim.

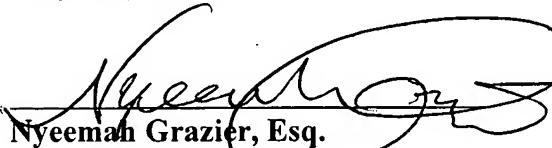
CONCLUSION

Any inquiry concerning this communication or earlier communications from the 15 examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

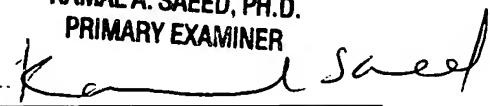
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

10 
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